DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m4990n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
December 19, 2000

WARNING LETTER

Mr. Michael Chanowich
President
Belford Seafood Co-Op
901 Port Monmouth Road
Belford, NJ 07718

FILE NO: 01-NWJ-13

Dear Mr. Chanowich:

We inspected your firm, located at 901 Port Monmouth Road, Belford, New Jersey, on October 17, 18, and 20, 2000, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your bluefish, mackerel, and small tuna to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1) You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for bluefish, mackerel, and small tuna list a critical limit, "visual evidence of decomposition" at the receiving critical control point that is not adequate to control the food safety hazard of histamine. Sensory analysis should include observations of odors of decomposition and is an indicator of histamine formation, but by itself is not adequate to control the hazard. FDA's *Fish and Fisheries Products Hazards and Controls Guide: Second Edition*, page 78 lists acceptable control strategy critical limits at the receiving critical control point for primary processors of histamine producing species.

2) You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for bluefish, mackerel, and small tuna list monitoring procedures at your receiving critical control point that are not adequate to control histamine. The investigator also noted that you are only recording an average temperature for your incoming fish. Each internal temperature of fish that you take should be recorded.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product (s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as an updated HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure or injunction under the Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union (EU) certificates.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054. If you have any questions, please contact Diane Radice at (973) 526-6006.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District